DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 20, 2015

Zimmer Spine, Incorporated
% Ms. Donna M. Semlak
Senior Regulatory Affairs Specialist
7375 Bush Lake Road
Minneapolis, Minnesota 55439

Re: K143626
Trade/Device Name: inVizia® Anterior Certical Plate System, SC-AcuFix® Ant-Cer Dynamic Cervical Plating System, SC-AcuFix® Slimline® Anterior Cervical Plate System, SC-AcuFix® Thinline® Anterior Cervical Plate System, Trinica® Anterior Lumbar Plate System, Trinica® Anterior Cervical Plate System and Trinica® Select Anterior Cervical Plate System, V2F™ Anterior Fixation System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: December 19, 2014
Received: December 22, 2014

Dear Ms. Semlak:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K143626

Device Name
inViZia® Anterior Cervical Plate System

Indications for Use *(Describe)*

The inViZia® Anterior Cervical Plate System is designed for anterior interbody screw fixation of the cervical spine at levels C2-T1.

The inViZia® Anterior Cervical Plate System is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusions in patients with degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), trauma (including fractures), tumors, deformity (defined as kyphosis, lordosis or scoliosis), pseudoarthrosis and/or failed previous fusions.

WARNING: This device is not approved for screw attachment to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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Indications for Use

Form Approved: OMB No. 0910-0120
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510(k) Number *(if known)*
K143626

Device Name
SC-AcuFix® Ant-Cer Dynamic Cervical Plating System

Indications for Use *(Describe)*

The SC-AcuFix® Ant-Cert Dynamic Anterior Cervical Plate System is indicated for use in the temporary stabilization of the cervical spine (C2-C7) during the development of solid spinal fusion inpatients with instability caused by the following: degenerative disc disease (as defined by neck pain of discogenic origin with denegation of the disc confirmed by patient history and radiographic studies), trauma (including fractures), tumor, spondylolisthesis, spinal stenosis, deformity (i.e. scoliosis, kyphosis, lordosis), pseudarthrosis, and failed previous fusions.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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510(k) Number *(if known)*
K143626

Device Name
SC-AcuFix® Slimline® Anterior Cervical Plate System

Indications for Use *(Describe)*

The Spinal Concepts Inc. (SCI) Anterior Cervical Plate System is indicated for use in the temporary stabilization of the cervical spine (C2-C7) during the development of solid spinal fusion inpatients with instability caused by the following: degenerative disc disease (as defined by neck pain of discogenic origin with denegation of the disc confirmed by patient history and radiographic studies), trauma (including fractures), tumor, spondylolisthesis, spinal stenosis, deformity (i.e. scoliosis, kyphosis, lordosis), pseudarthrosis, and failed previous fusions.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K143626

Device Name
SC-AcuFix® Thinline® Anterior Cervical Plate System

Indications for Use *(Describe)*

The SC-AcuFix® Thinline Anterior Cervical Plate System is indicated for use in the temporary stabilization of the cervical spine (C2-C7) during the development of solid spinal fusion inpatients with instability caused by the following: degenerative disc disease (as defined by neck pain of discogenic origin with denegation of the disc confirmed by patient history and radiographic studies), trauma (including fractures), tumor, spondylolisthesis, spinal stenosis, deformity (i.e. scoliosis, kyphosis, lordosis), pseudarthrosis, and failed previous fusions.

Type of Use *(Select one or both, as applicable)*

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See PRA Statement on last page.

510(k) Number *(if known)*
K143626

Device Name
Trinica® Anterior Lumbar Plate System

Indications for Use *(Describe)*

The Trinica® Anterior Lumbar Plate System is indicated for use via the lateral or anterolateral surgical approach above the bifurcation of the great vessels or via the anterior surgical approach, below the bifurcation of the great vessels. This system is indicated in the treatment of lumbar or lumbosacral (L1-S1) spine instability as a result of fracture (including dislocation and subluxation), tumor, degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), pseudoarthrosis, spondylolisthesis, scoliosis, lordotic deformities of the spine, spinal stenosis, or a failed previous fusion. .

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K143626

Device Name
Trinica® Anterior Cervical Plate System and Trinica® Select Anterior Cervical Plate System

Indications for Use *(Describe)*

The Trinica® and Trinica® Select Anterior Cervical Plate System is intended for anterior interbody screw fixation of the cervical spine at level C2-T1. The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusions in patients with degenerative disc disease (as defined by neck pain of discogenic origin confirmed by patient history and radiographic studies), trauma (including fractures), tumors, deformity (defined as kyphosis, lordosis or scoliosis), pseudoarthrosis and/or failed previous fusions.

WARNING: These devices are not approved for screw attachment to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

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Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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510(k) Number *(if known)*
K143626

Device Name
V2F™ Anterior Fixation System

Indications for Use *(Describe)*

The V2F Anterior Fixation System is indicated for use via the lateral or anterolateral surgical approach in the treatment of thoracic and thoracolumbar (T1-L5) spine instability as a result of fracture (including dislocation and subluxation), tumor, degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), scoliosis, kyphosis, lordosis, spinal stenosis, or a failed previous spine surgery.
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Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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zimmer spine	**510(k) SUMMARY** ***Anterior Cervical and Lumbar Plate Devices***

Date of Summary Preparation:	March 13, 2015
Submitter:	Zimmer Spine, Inc. 7375 Bush Lake Road Minneapolis, MN 55439 USA
Establishment Registration Number:	2184052 (Minneapolis)
Company Contact (Primary):	Donna M. Semlak Senior Regulatory Affairs Specialist Email: Donna.Semlak@zimmer.com Office: 952.857.5643 Email Fax: 952.857.5843
Common Name(s):	Appliance, Fixation, Spinal Intervertebral Body
Device/ Trade Names(s):	*inViZia*® Anterior Cervical Plate System *SC-AcuFix*® Ant-Cer Dynamic Cervical Plating System *SC-AcuFix*® Slimline® Anterior Cervical Plate System *SC-AcuFix*® Thinline® Anterior Cervical Plate System *Trinica*® Anterior Lumbar Plate System *Trinica*® *and Trinica*® Select Anterior Cervical Plate System *V2F*™ Anterior Fixation System
Device Classification:	Class II
Regulation Number and Product Code(s):	21 CFR § 888.3060 / KWQ *Spinal intervertebral body fixation orthosis*

Predicate Devices:

The primary predicate device for this submission is the currently marketed *Zimmer Spine Anterior Cervical and Lumbar Plate System* listed below. The purpose of this submission is to update product specific package inserts (IFU) with MRI Conditional language only.

Product Name	FDA 501(k) or PMA Numbers	Classification	Primary Code
V2F™ Anterior Fixation System	K122733	Class II	KWQ 21 CFR § 888.3060

Additional Predicate Devices:

Product Name	FDA 501(k) or PMA Numbers	Classification	Primary Code
inViZia® Anterior Cervical Plate System	K111796	Class II	KWQ 21 CFR § 888.3060
SC-AcuFix® Ant-Cer Dynamic Cervical Plating System	K052072	Class II	KWQ 21 CFR § 888.3060
SC-AcuFix® Slimline® Anterior Cervical Plate System	K990005	Class II	KWQ 21 CFR § 888.3060
SC-AcuFix® Thinline® Anterior Cervical Plate System	K013979	Class II	KWQ 21 CFR § 888.3060
Trinica® Anterior Lumbar Plate System	K140611	Class II	KWQ 21 CFR § 888.3060
Trinica® Anterior Cervical Plate System *Trinica*® Select Anterior Cervical Plate System	K132012	Class II	KWQ 21 CFR § 888.3060

There are no reference devices for this submission.

General Device Description:

The *Zimmer Spine Anterior Cervical and Lumbar Plate System*s are intended to provide stabilization of the spine during the development of a solid spinal fusion in patients per the system(s) indications at various spinal levels. The *Zimmer Spine Anterior Cervical and Lumbar Plate System*s consist of plates, bone screws and instruments necessary to implant the specific system. Bone screws are secured to the plate through locking caps and/or a Secure Ring® mechanism. The plates are available in various sizes and lengths and the bone screws are available in various diameters and lengths.

The *subject devices* are temporary implants to be implanted per the indications for use and/or the instructions of the surgical technique guide(s). These *subject implants* are intended to be removed after solid fusion has occurred.

The *Zimmer Spine Anterior Cervical and Lumbar Plate* implants (plates and bone screws) are manufactured from medical grade Ti-6Al-4V ELI titanium alloy. The system's instrumentation is manufactured from one (or more) of the following medical/surgical grade materials: stainless steel, plastic, aluminum, and silicone.

The *subject implants* are provided non-sterile and must be sterilized by the end-user/healthcare facility prior to use. The *subject implants* are designed for single-use only. The system's instrumentation is provided to the end-user/healthcare facility clean but not sterile. The end-user/healthcare facility ensures through cleaning and sterilization of instrumentation before use and the instrumentation may be reused. Selective *plate systems* contain drill bits and/or fixation pins that are provided to the end-user sterile and designed for single-use.

Indications for Use:

Product Name	Indications For Use
inViZia® Anterior Cervical Plate System	The *inViZia*® Anterior Cervical Plate System is designed for anterior interbody screw fixation of the cervical spine at levels C2-T1. The *inViZia*® Anterior Cervical Plate System is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusions in patients with degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), trauma (including fractures), tumors, deformity (defined as kyphosis, lordosis or scoliosis), pseudoarthrosis and/or failed previous fusions. WARNING: This device is not approved for screw attachment to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.
SC-AcuFix® Ant-Cer Dynamic Cervical Plating System	The *SC-AcuFix*® Ant-Cert Dynamic Anterior Cervical Plate System is indicated for use in the temporary stabilization of the cervical spine (C2-C7) during the development of solid spinal fusion inpatients with instability caused by the following: degenerative disc disease (as defined by neck pain of discogenic origin with denegation of the disc confirmed by patient history and radiographic studies), trauma (including fractures), tumor, spondylolisthesis, spinal stenosis, deformity (i.e. scoliosis, kyphosis, lordosis), pseudarthrosis, and failed previous fusions.
SC-AcuFix® Slimline® Anterior Cervical Plate System	The Spinal Concepts Inc. (SCI) Anterior Cervical Plate System is indicated for use in the temporary stabilization of the cervical spine (C2-C7) during the development of solid spinal fusion inpatients with instability caused by the following: degenerative disc disease (as defined by neck pain of discogenic origin with denegation of the disc confirmed by patient history and radiographic studies), trauma (including fractures), tumor, spondylolisthesis, spinal stenosis, deformity (i.e. scoliosis, kyphosis, lordosis), pseudarthrosis, and failed previous fusions.
SC-AcuFix® Thinline® Anterior Cervical Plate System	The *SC-AcuFix*® Thinline Anterior Cervical Plate System is indicated for use in the temporary stabilization of the cervical spine (C2-C7) during the development of solid spinal fusion inpatients with instability caused by the following: degenerative disc disease (as defined by neck pain of discogenic origin with denegation of the disc confirmed by patient history and radiographic studies), trauma (including fractures), tumor, spondylolisthesis, spinal stenosis, deformity (i.e. scoliosis, kyphosis, lordosis), pseudarthrosis, and failed previous fusions.
Trinica® Anterior Lumbar Plate	The *Trinica*® Anterior Lumbar Plate System is indicated for use via the lateral or anterolateral surgical approach above the bifurcation of the great vessels or via the anterior surgical approach, below the bifurcation of the great vessels. This system is indicated in the treatment of lumbar or lumbosacral (L1-S1) spine

Product Name	Indications For Use
System	instability as a result of fracture (including dislocation and subluxation), tumor, degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), pseudoarthrosis, spondylolisthesis, scoliosis, lordotic deformities of the spine, spinal stenosis, or a failed previous fusion.
Trinica® Anterior Cervical Plate System *Trinica*® Select Anterior Cervical Plate System	The *Trinica*® and *Trinica*® Select Anterior Cervical Plate System is intended for anterior interbody screw fixation of the cervical spine at level C2-T1. The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusions in patients with degenerative disc disease (as defined by neck pain of discogenic origin confirmed by patient history and radiographic studies), trauma (including fractures), tumors, deformity (defined as kyphosis, lordosis or scoliosis), pseudoarthrosis and/or failed previous fusions. WARNING: These devices are not approved for screw attachment to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.
V2F™ Anterior Fixation System	The *V2F™* Anterior Fixation System is indicated for use via the lateral or anterolateral surgical approach in the treatment of thoracic and thoracolumbar (T1-L5) spine instability as a result of fracture (including dislocation and subluxation), tumor, degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), scoliosis, kyphosis, lordosis, spinal stenosis, or a failed previous spine surgery.

Summary of Technological Characteristics:

The technological characteristics remain the same between the subject *Zimmer Spine Anterior Cervical and Lumbar Plate System*s as the predicate devices listed above. There are no changes to the implants (plate and bone screws) and instrumentation within this submission. This submission is only proposing labeling updates regarding interactions with magnetic fields during Magnetic Resonance Imaging (MRI) with respect to patient safety.

All the technology characteristics remain the same: same system's intended use, same mechanical and functional scientific technology; same materials and the same substantially equivalent performance characteristics.

Summary of Performance Testing:

Magnetic Resonance Imaging (MRI) testing of Plate implants contained in the *Zimmer Spine Anterior Cervical and Lumbar Plate System*s were assessed and tested appropriately to design controls; i.e. ASTM Standards.

- ASTM F2052: 2006 Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment
- ASTM F2119: 2007 Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants
- ASTM F2182: 11a* Standard Test Method of Measurement of Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging

- ASTM F2213: 2006 Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment

No further device performance (bench) testing was required for this submission.
The performance (bench) testing remains the same for the currently marketed *Zimmer Spine Anterior Cervical and Lumbar Plate System*s listed as above predicates.

No further sterilization, biocompatibility and cytotoxicity evaluation and/or testing were required for this submission. The sterilization, biocompatibility and cytotoxicity testing remains the same for the currently marketed *Zimmer Spine Anterior Cervical and Lumbar Plate System*s listed as above predicates.

Substantial Equivalence

Zimmer Spine considers the subject *Zimmer Spine Anterior Cervical and Lumbar Plate System*s to be substantially equivalent to the currently marketed (predicate) *Zimmer Spine Anterior Cervical and Lumbar Plate System*s listed as above because:

- No changes to the intended use,
- No changes to mechanical and functional performance,
- No changes to the functional scientific technology,
- No changes to the implants,
- No changes to the instrumentation,
- No changes to the technological characteristics mentioned above
- No changes to the surgical technique steps